

REMARKS

These remarks are in response to the Office Action mailed May 31, 2005. Claim 6 has been canceled without prejudice to Applicants' right to prosecute the canceled subject matter in any divisional, continuation, continuation-in-part or other application. Claim 1 has been amended to correct the letter and number system and to clarify the invention. Support for a combination of, for example, nutrient medium and BSN-CM can be found at page 7, lines 16-18. Support for the amendments to claim 1(c) can be found, for example, at page 16, line 3. No new matter is believed to have been introduced.

I. CLAIM OBJECTION

Claim 1 stands objected for lacking "d" in the numbering/lettering system. Applicants have amended claim 1 to recite "(d)". Accordingly, the objection may be withdrawn.

II. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 1, 5-7, 10 and 12 stands rejected under 35 U.S.C. §112, first paragraph, because the specification while being enabling for constructing a mammalian tissue or a fragment thereof, comprising the method of claim 1, wherein the conditioned medium is BSN cell cultured medium (BSN-CM), allegedly does not reasonably provide enablement for construction of a mammalian tissue or a fragment thereof, comprising any "conditioned medium". Claim 6 has been canceled, thus the rejection is moot with respect to this claim. Applicants respectfully traverse this rejection.

Although Applicant has amended claim 1 to recite BSN-CM, Applicant respectfully submits that other conditioned medium did show branching morphogenesis, however, it was not as extensive and effective as BSN-CM. Thus, Applicants submit that the specification is being taken out of context when Applicants recite at page 13, "Only BSN-CM could promote **extensive** branching morphogenesis. . ." (emphasis added). In other words, other conditioned media can provide branching morphogenesis, but BSN-CM provided "extensive" branching.

Applicants believe the foregoing amendments and remarks overcome the rejection. Accordingly, Applicant respectfully requests withdrawal of the rejection.

Claim 6 stands rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The claim allegedly contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, had possession of the claimed invention. Applicants have canceled claim 6; however, Applicants respectfully traverse this rejection.

The Office Action admits that Applicants have provided conditioned growth medium that comprises a growth promoting constituent and/or inducer of differentiation (see, e.g., the Office Action at page 7). Applicants claim 6 recites, ". . . wherein the added conditioned medium comprise a growth promoting constituent or inducer of differentiation or morphogenesis." Applicants submit that claim 6 is not claiming the constituent, but merely further defining the "conditioned medium" as comprising such a constituent. Applicants submit that the specification teaches that the conditioned growth medium induces growth/differentiation/morphogenesis. Thus, Applicants were in possession of a growth medium comprising factors that induced growth/differentiation/morphogenesis as recited by claim 6. Thus, the claim is enabled by the specification.

III. REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 1, 5-7, 10 and 12 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 has been canceled, thus the rejection is moot with respect to this claim. Applicants respectfully traverse this rejection.

The Office Action alleges that the term "conditioned medium" is indefinite. Applicants have addressed this term above.

The Office Action further alleges that it is unclear what "branches" refers to in claim 1(a)(ii). Applicants respectfully submit that branching morphogenesis is a well recognized tissue process. Furthermore, the one of skill in the art to which the

invention pertains would understand the term: "to form multiple branches". For example, branching is a particular form of tissue morphogenesis whereby ducts are formed in a developing tissue. Accordingly, the term "branching" or "branching morphogenesis" are recognized terms in the art and therefore are not indefinite.

The Office Action alleges that the term "medium" is unclear because it is not clear whether it is different from BSN-CM. Applicants have amended claim 1 to recite that the medium is "nutrient medium" to make it clear that it is not BSN-CM. Support for a mixture of "nutrient medium" and "BSN-CM" can be found, for example, at page 7, lines 16-19; and in claim 1 as originally filed.

The Office Action further rejects claim 1 because the recitation of "substrate deprivation" and "soluble factors" is allegedly indefinite. Applicants respectfully submit that "substrate deprivation" is a term of art that is well known. Substrate deprivation is a very well-known phenomenon, described for several kinds of solutes, such as neutral amino acids (*J Biol Chem* 256: 3191-3198, 1981; *Biochim Biophys Acta* 266: 407-421, 1972), and, in lower organisms, inositol itself (*Mol Biochem Parasitol* 104: 121-130, 1999). So when the Examiner questions the culturing of the cells "on a substrate", the Examiner is misguided in that the "substrate" refers to, for example, nutrient-type substrates. Thus, Applicants submit that the term "substrate deprivation" is not indefinite. Furthermore, the specification identifies the use of "soluble growth factors". The claims have been amended to refer to "soluble growth factors". Such soluble growth factors are known in the art.

The Office Action also alleges that the term "combining" in claim 1(c) is indefinite. Applicants respectfully submit that the term is not indefinite to someone of skill in the art. For example, the specification refers to the combining as combining the branch tip buds and mesenchyme cells and co-culturing the cells together. If the Examiner would prefer the term "coculturing", the Examiner is invited to call the undersigned; however, Applicants submit that the combining is a process that is described in the art and further described in the specification to refer to combining the two cell types and, pursuant to 1(d), co-culturing the cells together.

The Office Action also alleges that claim 1(d) is indefinite as it is allegedly unclear what conditions are needed for vasculogenesis. Applicants have amended claim 1(d) to indicate that the cells are cultures to maintain cell growth. Such cell

culture techniques are well known in the art and include a variety of cell culture media including, for example, DMEM/F12 with 10%FCS.

Applicants believe that the foregoing remarks and amendments overcome the rejection. Accordingly, Applicants respectfully request withdrawal of the §112, second paragraph rejections.

IV. REJECTION UNDER OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 1 and 12 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 26, 29, and 38 of copending Application No. 10/608,783. Applicants respectfully traverse this rejection.

Applicants submit that it appears that the Examiner is picking and choosing particular elements in the claims of both applications to render an obviousness-type double patenting rejection. For example, at page 7 of the Office Action, it is alleged that steps (a) and (b) appear to be obvious variations. The Examiner is respectfully reminded that an obviousness rejection must be based upon the claimed invention as a "whole" (see, e.g., *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick*, 221 USPQ 481, 488 (Fed. Cir. 1984)). Thus, Applicants respectfully submit that there is not a prima facie case of obviousness. However, in order for both the Examiner and the Applicants to assess the alleged obviousness-type double patenting, the Examiner is respectfully requested to hold this rejection in abeyance until such time as one or the other of the applications contains allowable subject matter.

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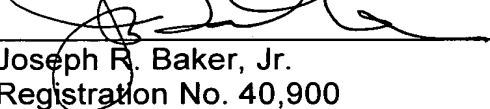
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No fee is believed to be due with respect to the filing of the present response. However, the Commission is authorized to charge any required fee, or credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

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Date: July 28, 2005

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